

TITLE: NEW PRODUCT, DISCONTINUATION, OR CHANGE

ATTACHMENT 2 – PRODUCT MODIFICATION

Section 1: QA/Document Control:Part Number: PIHBV6508 HBV Longitudinal Panel (14 now 13x 1mL)Description of Modification: Crossed out member 11PCA/CCR Number: CCR23056

Move Document(s) to Website Transition Folder and notify Website Coordinator	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> N/A
Move a copy of this Product Modification (Attachment 2) to Website Transition Folder/Copy of completed CCR Form Printed	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> N/A
Notify Website Coordinator that all documents have been moved	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> N/A

Name: Amel Bennett Date: 06-09-2023**Section 2: Sales and Marketing:**

Notify all distributors and recent clients of new Sales and Marketing information if relevant using Attachment 6 (Distributor Notification)	<input type="checkbox"/> Yes	<input type="checkbox"/> N/A
Provide updated PI, SDS and any product attributes to the Supplier Change Team supplierchanges@antylia.com	<input type="checkbox"/> Yes	<input type="checkbox"/> N/A
Forward to the Website Coordinator	<input type="checkbox"/> Yes	<input type="checkbox"/> N/A

Name: _____ Date: _____

Section 3: Website Coordinator:

Make updates to the website and GDP	<input type="checkbox"/> Yes	<input type="checkbox"/> N/A
Notify Sales and Marketing, Dept Manager/Director, and Document Control of the additions via e-mail and attach a copy	<input type="checkbox"/> Yes	<input type="checkbox"/> N/A

Name: _____ Date: _____

TITLE: DOCUMENT CONTROL

ATTACHMENT 1 – CHANGE CONTROL REQUEST FORM

COPY

CHANGE DESCRIPTION:

ORIGINATOR: Barbara Anfilaro DATE: 6-2-23
DOCUMENT NUMBER: PI HBV6508 CHANGE CONTROL NUMBER: CCR 23056
DOCUMENT TITLE: HBV Longitudinal Panel Part number HBV6508
CURRENT REVISION: Rev 04 NEW REVISION: Rev 05
CHANGE REQUESTED: Cross out member 11

REASON FOR CHANGE: no longer in Panel

SIGNATURE: Barbara Anfilaro DATE: 6-2-23

CHANGE ASSESSMENT: (FILLED OUT BY CHANGE CONTROL BOARD ONLY)

Will this Document Change require a PDC or PPC? (Check one) YES ☐ NO ☒

If No, why not? * Product Modification Form needed

Will this change or affect the QMS, processes, product, website, or other documents? (Check one) YES ☒ NO ☐

If Yes, list the affected areas: website

Change Risk Level to the QMS (Check one) N/A ☐ LOW ☐ MEDIUM ☒ HIGH ☐

Justify Risk: Customer facing document

Will this Change be implemented retroactively? YES ☐ NO ☒

If Yes, provide details: _____

Does this Document Change require training? (Check one) YES ☐ NO ☒

If Yes, indicate personnel/departments. If No, specify why not? Product literature

CHANGE CONTROL BOARD SIGN-OFF:

Lynnda Muro 6-6-23 Sharon K. Gleich 6/7/23
Maloff 6-7-2023

REQUEST DISPOSITION: Date of last CCB approval/ Initials: 06-07-2023 JLB

All required actions are complete and the document is now effective:

SIGNATURE: Janet Bennett DATE: 06-09-2023



HBV Longitudinal Panel Part Number: HBV6508

*These reagents are not a substitute for the mandatory positive and negative control reagents provided with licensed test kits.
For Research Use Only. Not for use in diagnostic procedures.*

PANEL NUMBER	DATE OF DRAW	ORTHO VITROS ECI ANTI-HIV ½ TEST DATE: 8/4/2014	ORTHO VITROS ECI ANTI-HCV TEST DATE: 8/4/2014	ABBOTT HBsAg TEST DATE: UNK	ORTHO VITROS ECI HBsAg TEST DATE: 8/4/2014	ABBOTT ANTI-HBc TOTAL TEST DATE: UNK	ORTHO VITROS ECI ANTI-HBc TOTAL TEST DATE: 8/4/2014	ABBOTT ANTI-HBc IgM TEST DATE: UNK
6508-01	05/16/01	0.04	0.08	>40.8	1480	0.04	0.08	>6.9
6508-02	05/28/01	0.09	0.07	>40.8	2790	0.05	0.10	>6.9
6508-03	06/11/01	0.09	0.06	>40.8	3100	0.04	0.09	>6.9
6508-04	06/28/01	0.10	0.03	>40.8	6760	0.05	0.05	>6.9
6508-05	07/11/01	0.06	0.03	>40.8	6670	0.06	0.46	>6.9
6508-06	07/25/01	0.09	0.05	7.1	0.60	0.04	0.15	3.1
6508-07	08/08/01	0.08	0.04	0.08	0.07	0.03	0.10	3.0
6508-08	08/22/01	0.07	0.05	0.04	0.07	0.03	0.07	3.4
6508-09	09/05/01	0.08	0.05	0.09	0.08	0.04	0.07	2.9
6508-10	09/19/01	0.06	0.05	0.09	0.07	0.03	0.06	2.9
6508-11	10/03/01	0.08	0.05	0.09	0.06	0.04	0.05	2.9
6508-12	10/16/01	0.06	0.05	0.04	0.07	0.07	0.05	2.5
6508-13	11/20/01	0.06	0.02	0.08	0.08	0.08	0.03	2.2
6508-14	12/11/01	0.06	0.03	0.02	0.09	0.08	0.02	2.1
6508-15	12/25/01	0.03	0.04	0.13	0.08	0.07	0.05	2.2

PANEL NUMBER	ORTHO VITROS ECI ANTI-HBc IgM TEST DATE: 8/4/2014	DIASORIN ANTI-HBe TEST DATE: UNK	ORTHO VITROS ECI ANTI-HBe TEST DATE: 8/4/2014	ABBOTT ANTI-HBs QUANT TEST DATE: UNK	ORTHO VITROS ECI ANTI-HBs QUANT TEST DATE: 8/4/2014	ORTHO VITROS ECI HBeAg TEST DATE: 8/4/2014	DIASORIN HBeAg TEST DATE: UNK
6508-01	QNS	0.6	0.65	0.3	QNS	0.60	0.3
6508-02	3.84	0.9	0.28	0.3	1.8	0.39	0.3
6508-03	3.91	0.9	0.33	0.3	1.7	0.37	0.3
6508-04	3.88	1.0	0.62	0.2	1.5	0.45	0.3
6508-05	3.40	0.6	QNS	0.3	1.3	0.13	0.5
6508-06	1.83	0.1	19.2	0.4	3.8	0.11	0.07
6508-07	4.41	0.4	33.4	4.2	9.8	0.41	0.37
6508-08	1.58	0.1	16.9	1.95	19.2	0.11	0.07
6508-09	1.64	0.1	17.9	4.3	54.3	0.11	0.12
6508-10	1.50	0.1	10.4	7.5	116	0.11	0.08
6508-11	1.37	0.2	12.8	10.4	150	0.42	0.44
6508-12	1.33	0.2	8.15	9.3	210	0.11	0.04
6508-13	1.23	0.2	4.43	13.0	232	0.11	0.12
6508-14	0.95	0.3	2.72	10.9	184	0.11	0.08
6508-15	1.21	0.4	2.70	11.6	228	0.10	0.12

Notes on Data:

1. This panel is for **Research Use Only. Not for use in diagnostic procedures.**
2. Data is generated at ZeptoMetrix™ LLC and by our Laboratory Partners in the United States and Europe.
3. All specimens collected in this longitudinal series are unadulterated 4% sodium citrated plasma samples collected from a single donor in the United States.
4. No preservatives have been added.

ZeptoMetrix LLC • 25 Kenwood Circle, Franklin, MA 02038 • Tel (508) 553-5800 • Fax (508) 520-1525
This Product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.
For Customer Support, please visit www.zeptometrix.com or email zepto.customerservice@antylia.com

PIHBV6508 Rev05
Effective Date: 06/09/2023